PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
234		
International application No.	International filing date (*day/month/year*)	Priority Date (*day/month/year*)
PCT/KR 2004/003309	15 December 2004 (15.12.2004)	16 December 2003 (16.12.2003)

International Patent Classification (IPC) or national classification and IPC

IPC[8]: ***C07D 211/90*** (2006.01)

Applicant

SK CHEMICALS CO. LTD.

1. This international preliminary examination report has been prepared by this International Preliminary Examination Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I. ☒ Basis of the opinion
- II. ☐ Priority
- III. ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV. ☐ Lack of unity of invention
- V. ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI. ☐ Certain documents cited
- VII. ☐ Certain defects in the international application
- VIII. ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11 July 2005 (11.07.2005)	7 April 2006 (07.04.2006)
Name and mailing address of the IPEA/AT Austrian Patent Office Dresdner Straße 87 A-1200 Vienna Facsimile No. 1/53424/200	Authorized officer SLABY S. Telephone No. 1/53424/348

Form PCT/IPEA/409 (cover sheet) (July 1998)

Express Mail No. EV746687240US

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/KR 2004/003309

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____.

☐ the claims, Nos. _____.

☐ the drawings, sheets/fig _____.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as „originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-11	YES
	Claims	----	NO
Inventive step (IS)	Claims	----	YES
	Claims	1-11	NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims	----	NO

Citations and explanations (Rule 70.7)

The present application relates to amlodipine gentisate (2,5-dihydroxy benzoate).

The following documents are considered relevant:

D1 EP 244944 A2
D2 WO 0279158 A1
D3 WO 0389414 A1

D1 discloses various pharmaceutical salts of amlodipine including mesylate, besylate. tosylate, succinate, salicylate and acetate.
D2 discloses amlodipine camsylate and D3 discloses amlodipine nicotinate.

Since none of the cited documents discloses amlodipine gentisate, the subject matter is considered as novel.

D1 discloses the salicylate salt of amlodipine, which differs from the gentisate salt only in a hydroxyl substituent in the benzene ring. Such a variation is considered to belong to routine experimentation of a person skilled in the art.
Moreover, the surprising effect of the gentisate salt is not apparent from the comparative test in the description. Although tables 6 and 7 show higher activity of the gentisate salt, the result is not comparable, since the besylate salt is a racemic mixture while the gentisate salt is an (S)-isomer.
The process for the preparation of amlodipine gentisate according to claims 3-8 is a conventional technique for the preparation of acid addition salts, since it is also disclosed in D2 and D3.
An inventive step cannot be acknowledged for the subject matter of the present claims.

Industrial applicability is given.